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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/779,689	02/08/2001	Kiran M. Das	13257-00031	6769

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EXAMINER
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ART UNIT	PAPER NUMBER
1644	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Offic Action Summary	Application No. 09/779,689	Applicant(s) DAS, KIRAN M.	
	Examiner Margaret E Jamroz	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 February 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) *1-11* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *6* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Claims 1-15 are pending.

Applicant's election of Group VI (claims 12-15) in Paper No. 8 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-11 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b) as being drawn to non-elected inventions.

Claims 12-15 are under consideration in the instant application.

2. Applicant's IDS, filed 01/09/2002 (Paper No. 6), is acknowledged, however, the references for the citations with the page numbers crossed out were considered only with respect to the Abstract; were crossed out because they were not found in the submitted papers; or the full citation was not provided.

3. The disclosure is objected to because of the following informalities: on page 5, lines 8-9, applicant should add "and" after inflammatory bowel disease.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112.

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 12-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claim 12 is indefinite in the recitation of "autoantigen response to hTM". It is unclear whether hTM is the autoantigen or if an autoantibody response is made to hTM.

7. Claim 12 is indefinite and ambiguous because although it recites detection of CEP-hTM complexes, it is unclear as to what compound is used to detect the complexes.

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 12-15 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a diagnostic method for detecting ulcerative colitis and inflammatory bowel disease in intracellular and extracellular spaces of colon epithelial cells, skin and biliary epithelium, ciliary epithelium in the eye, and chondrocytes, and in the extracellular spaces of the large intestines comprising detecting CEP-hTM complexes with antibodies against CEP and hTM, does not reasonably provide enablement for a diagnostic method for detecting any other disease in intracellular and extracellular spaces of any other cell type comprising detecting CEP-hTM complexes with antibodies against CEP and hTM or any other detection reagent. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The specification does not enable one of skill in the art to practice the invention as claimed without undue experimentation.

Applicant has not taught how to detect any disease comprising detecting CEP-hTM complexes in extracellular and intracellular spaces of any cell or tissue.

Applicant discloses in the specification on page 7, paragraph 2 that in the gastrointestinal tract, CEP is expressed only in colon epithelial cells, which is why ulcerative colitis is restricted to the colon. Further, in extracolonic sites, CEP is expressed in skin and biliary epithelium, ciliary epithelium in the eye, and in chondrocytes, all of which are organs and tissues commonly involved with inflammatory bowel disease.

With such restricted expression of CEP and the known fact that "the specific interaction between CEP and the autoantigen hTM is known to be a fundamental element in the development of inflammatory bowel disease and ulcerative colitis as disclosed on page 5, paragraph 2, applicant is not enabled for any other diagnostic method to detect any other disease in any other extracellular or intracellular space of any other cell or tissue.

Applicant discloses on pages 14-20 of the specification methods of detecting CEP-hTM complexes in intracellular spaces, on the surface of colon epithelial cells, and in extracellular spaces of colon epithelial cell lines using antibodies against CEP and hTM. Applicant has not taught how to make and/or use any other detection reagent to identify CEP and hTM.

The claims as written encompass an unlimited number of detection agents. Applicant is relying the disclosure of a single detection agent (i.e. antibodies against CEP and hTM) to support an entire genus of detection agents, such as labeled polypeptides. It is well known that minor structural differences among even structurally related compounds or compositions can result in substantially different biology, expression, and pharmacology of proteins. Without sufficient guidance to, and a knowledge of which other "reagent" could bind to CEP and hTM, one skilled in the art would require an undue amount of experimentation to determine which other reagents are effective as "detection" reagents.

Reasonable correlation must exist between the scope of the claims and scope of enablement set forth. In view of the quantity of experimentation necessary, the limited working examples, the unpredictability of the art, the lack of sufficient guidance in the specification, and the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

10. Claims 12-15 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant is in possession of a diagnostic method for detecting ulcerative colitis and inflammatory bowel disease in intracellular and extracellular spaces of colon epithelial cells, skin and biliary epithelium, ciliary epithelium in the eye, and chondrocytes, and in the extracellular spaces of the large intestines comprising detecting CEP-hTM complexes with antibodies against CEP and hTM,

Applicant is not in possession of a diagnostic method for detecting any other disease in intracellular and extracellular spaces of any other cell type comprising detecting CEP-hTM complexes with antibodies against CEP and hTM or any other detection reagent.

Applicant has disclosed a diagnostic method utilizing a single reagent (i.e. an antibody); therefore, the skilled artisan cannot envision all the contemplated "reagent" possibilities recited in the instant claims. Consequently, conception in either case cannot be achieved until a representative description of the structural and functional properties of the claimed invention has occurred, regardless of the complexity or simplicity of the method. Adequate written description requires more than a mere statement that it is part of the invention. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993).

The specification fails to define all detection reagents. The lack of sufficient limitations would therefore allow for all types of reagents in addition to antibodies. Therefore, the skilled artisan cannot envision all the contemplated "reagents" recited in the instant claims. Adequate written description requires more than a mere statement that it is part of the invention. A description of a genus of polypeptide sequences may be achieved by means of a recitation of a representative number of "reagents" falling within the scope of the genus, or of a recitation of structural features common to the genus, which features constitute a substantial portion of the genus. Regents of the University of California v. Eli Lilly&Co., 119F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.). Consequently, Applicant was not in possession of the instant claimed invention. See University of California v. Eli Lilly and Co. 43 USPQ2d 1398.

Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

12. Claims 12-15 are rejected under 35 U.S.C. 102(a) as being anticipated by Kesari et al. (*Clin Exp Immunol* 1999; 118: 219-227).

Kesari et al. teach a diagnostic method of detecting a disease (i.e. ulcerative colitis) associated with CEP-hTM complexes comprising detecting CEP-hTM complexes in an affected tissue (e.g. in extracellular and intracellular spaces of colon epithelium) with antibodies against CEP and hTM (see the entire document, the Materials and Methods in particular). Kesari et al. further teach that CEP expressed in colon epithelial cells, skin and biliary epithelium, ciliary epithelium in the eye and chondrocytes, and therefore, CEP-hTM complexes may be indicative of inflammatory bowel disease (see page 226 in particular).

Therefore, the Kesari et al. reference anticipates the claimed invention.

13. No claim is allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Megan Jamroz, whose telephone number is (703) 308-8365. The examiner can normally be reached Monday to Friday from 8:00 to 4:30. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached at (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Margaret (Megan) Jamroz, Ph.D.
Patent Examiner
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February 27, 2002

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